
An Analysis and Evaluation of Certificate of Need
Regulation in Maryland

Acute Inpatient Obstetric Services

*Response to Written Comments on the
Staff Recommendation*

MARYLAND HEALTH CARE COMMISSION

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An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Acute Inpatient Obstetric Services

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I. Introduction

The Maryland Health Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Acute Inpatient Obstetric Services*, presented seven alternative regulatory strategies to the current Certificate of Need requirement to establish that acute care service. These options include: complete deregulation from the CON review process; expansion of the CON program to more closely review service closures; maintain the CON program as it currently exists; and various strategies to replace CON with other kinds of government oversight.

The September 15, 2000 paper *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Acute Inpatient Obstetric Services; Summary and Analysis of Public Comments and Staff Recommendation*, weighed the public comments received on the working paper, and recommended that the Commission accept Option 4, "Creation of a Certificate of Need Exemption Process for New Obstetric Services". Option 4 proposed¹ the development of a new model for Commission review of proposals for new hospital obstetric services by statutorily expanding the use of the Certificate of Need exemption process.² The primary objective of this option is to change the way the State Health Plan's (SHP) need projection methodology is applied in the review of proposals for new obstetric services. The threshold requirement of consistency with the SHP's need projections would no longer act as a barrier to approval of new services. The public policy objectives of access (including need), quality and cost effectiveness would be revised to be more consistent with the current health care environment. Commission review and approval of a proposed new obstetric service would apply these revised and re-prioritized health policy goals.

The *Summary and Analysis of Public Comments and Staff Recommendation* was released for public comment after the Commission's September 15, 2000 meeting. Comments were received on this *Staff Recommendation* from the following, and have been distributed separately:

¹ The staff's recommendation in section V incorporates a refinement to the way the objective of Option 4 is implemented. The basic goal remains the same, as described in section III.

² The Commission's statute provides for an exemption from the requirement to obtain a Certificate of Need in certain circumstances deemed desirable by the General Assembly. In an exemption process, Commission approval is granted but a CON is not required, if the Commission finds that the proposal meets the following four statutory tests: (a) is pursuant to a merger or consolidation; (b) is in the public interest; (c) is not inconsistent with the SHP; and (d) will result in more efficient and effective delivery of services.

1. Anne Arundel Medical Center – Martin L. Doordan, President
2. Carroll County General Hospital – John M. Sernulka, President and CEO
3. Dimensions Healthcare System – Stephen J. Sfekas, Esquire
4. Doctors Community Hospital, North Arundel Hospital, Suburban Hospital, and University of Maryland Medical System – Philip B. Down, President & Chief Executive Officer; James R. Walker, President & CEO; Brian G. Grissler, President & Chief Executive Officer; and Morton I. Rapoport, M.D., President and Chief Executive Officer
5. Holy Cross Hospital – Kevin J. Sexton, President and CEO
6. Montgomery County Department of Health and Human Services – Madeline Turkeltaub, Chair, Montgomery County Commission on Health
7. St. Agnes HealthCare – Robert W. Adams, President/CEO

II. Summary of the Public Comments on the Staff Recommendation

Anne Arundel Medical Center states that it is not opposed to a fundamental restructuring of the CON process, but only if the restructuring is applied to all services regulated by the Commission. AAMC would oppose selective replacement of CON for obstetrics alone if it is used to eliminate CON for obstetrics only. They state that any new model of regulatory oversight should apply to all services or to not at all. AAMC also notes that this option results in no benefits to access, quality, or cost effectiveness. AAMC also questions the advantage of this option with respect to the Commission's role 'to encourage downsizing' of the hospital system. Finally, AAMC disagrees with staff's analysis of the meaning of HB 994 regarding the ability of merged hospital systems to move beds across county lines to create a new obstetric service.

Carroll County General Hospital suggests that the Commission not accept staff's recommendation, stating that staff's analysis does not support Option 4. CCGH states that there is no reason provided to change the existing law to ease the requirements to establish a new obstetric program. CCGH also says that a decision on Option 4 should be deferred until the exact criteria on which the exemption process are developed and reviewed. CCGH states that Option 4 is preferable to complete deregulation of obstetric services. Finally, CCGH disagrees with staff's analysis of HB 994 regarding merged hospital systems.

Dimensions Healthcare System believes that Option 4 is contrary to the Commission's mission to ensure appropriate access to high quality medical services at a reasonable cost, and to advance the public interest rather than the private interests of particular providers. Dimensions states that access to obstetric services is excellent, and that making market entry easier could harm access if there is a negative impact on the few providers that serve a large proportion of difficult, expensive, under-insured high-risk births. Dimensions states that Option 4 is "substantively flawed and procedurally deficient". Stating that the role of the CON process is to determine the impact of a project on the public, Dimensions notes that the CON exemption process is an expedited process created by the General Assembly for situations where there are compelling reasons for it, and affords no opportunity for affected

parties to participate in the review process.³ Dimensions also believes that relaxing CON requirements (Option 4) might be appropriate if there were a large anticipated need for new obstetrical capacity.

The letter from Doctors Community Hospital, North Arundel Hospital, Suburban Hospital and the University of Maryland Medical System (“the consortium”) supports Option 4 with certain significant modifications. Because the consortium believes that a statutory change is not required to accomplish the objective proposed by Option 4, creating a new CON exemption for new services would not be necessary. The consortium states that eliminating the threshold requirement to demonstrate need consistent with the SHP’s need projection can be accomplished within the Commission’s current authority. They suggest a modified CON process with revised approval policies in the State Health Plan that would change the focus from need prohibiting new development. In addition, the consortium points out that modifying the current CON program in this way would continue to allow existing providers to participate in the review process and address the impact of a proposed new program. The consortium also continues to support complete deregulation of obstetric services (Option 7).

Holy Cross Hospital believes that Option 4 would compromise the application of consistent principles. HCH does not support treating obstetric services differently than other inpatient acute services, specifically open heart surgery services. HCH also states that adding capacity without a demonstrated need will increase costs to the system. HCH notes that there is frequently tension among the competing interests of cost effectiveness, access and quality, and that the State’s role is to balance these interests. HCH states that eliminating the need component of the review process will reduce the State’s effectiveness in advancing its interests in cost effectiveness, while having little to no effect on access or quality. HCH also says that the purpose of the exemption process, to allow for an expedited review of actions deemed desirable by the General Assembly, does not apply to obstetric services. HCH also states that applying the exemption process to obstetric services presupposes that allowing additional obstetric programs is deemed desirable by the General Assembly, which is a ‘shaky supposition’. Finally, HCH supports Option 4’s call for an update of the SHP to better align its criteria and standards with the current health care environment, and suggests appropriate criteria for a revised SHP.

The Montgomery County Department of Health and Human Services, Commission on Health reiterates its earlier statements that CON regulation is not needed, and that local population-based planning strategies can determine the need for obstetric services. The Department did not specify those strategies or describe how they would be used to determine need for new services.

St. Agnes Hospital supports Option 4, given that only preliminary information is available on the criteria and standards to be used for proposed new programs. SAH urges the

³ Dimensions is incorrect in its statement that the exemption process does not provide for publication of notice of the proceeding, or allow affected parties to receive notice or to participate in the review. COMAR 10.24.01.04C requires the Commission to publish notice of the receipt of an exemption request in the *Maryland Register* and in at least one daily newspaper in the affected area; and requires the Commission to solicit comments and relevant information from the affected public in evaluating whether the project is in the public interest.

Commission to consider the long term ramifications of flat or declining use rates, large capital requirements for developing a new service, critical nursing shortages projected into the future, and increased system costs due to underutilized system capacity in developing the criteria and standards.

III. Staff Response and Analysis

Staff believes that the objective of Option 4, changing the way the need projections are applied in CON reviews, offers advantages over both retaining the current CON program for obstetric services without modifications, and over complete deregulation from CON. While there is merit to the view that there is no need to modify the current process, a case can be made that additional flexibility is warranted. The CON program can benefit from a shift in emphasis among the planning priorities and principles contained in the State Health Plan.

Certificate of Need was first developed as a tool to help guide a growth industry so that new facilities and services were allocated according to a plan guided by the public interest. The objective was to guide improvements in access through locating additional capacity where need was demonstrated. Beginning in the 1990s, however, the emphasis shifted to cost containment and quality improvement. As a consequence, the types of projects reviewed by the CON program also changed – far fewer new facilities and more consolidations and closures. However, the State Health Plan has not responded by changing its emphasis on need for basic acute care services. The Commission's role in overseeing and ensuring access to care has shifted, and now both the SHP and CON review must increasingly guide downsizing, prevent overbuilding, and seek quality improvements while maintaining access and containing costs.

The salient difference in today's health care environment is that need for new facilities is no longer a driving force, yet review of a proposal for a new basic care service like obstetrics still has a threshold need requirement. The SHP's current need projection policies prevent approval of new obstetric service if no need is projected for the jurisdiction. Under the current SHP policies and standards, only if need can be demonstrated according to the State Health Plan's current need projection methodology, will the merits of the proposal be considered.

The basic principle behind Option 4 is a different approach to need and access for basic obstetric services. Option 4 supports the elimination of the SHP's threshold need requirement but will require an applicant to demonstrate that the proposed project is needed. Alternative criteria regarding need will be developed to better address the evolving role of State oversight. As the role of need changes, so too will the other planning principles.

The revision of the State Health Plan will include development of new or revised criteria related to cost effectiveness, quality of care, impact of a new program on existing ones, and facility closures and consolidations. Although obstetrics is a basic hospital service, it has a link with specialized service component, as evidenced by the State's perinatal referral system and neonatal intensive care (NICU) services. Thus, approval of new services should be based

on criteria and standards consistent with the principles and standards for the perinatal system and the Commission's NICU plan chapter for a well-planned system of care.

Many commenters expressed concern about the potential negative impact of new obstetric services on existing providers. However, Option 4, if approved, will not result in automatic approvals of new programs, and never contemplated doing so. A major advantage of Option 4 over removing obstetrics from CON coverage is that some level of Commission review and approval of proposed new obstetric services will still be required. Staff believes that this continuing oversight protects the public interest, but also gives providers significantly more flexibility. The additional criteria and standards for approval of a new obstetric service will become part of the State Health Plan (COMAR 10.24.10), and as such will be adopted according to the rules for regulatory changes.

Although the comments from the consortium describe a "modified CON process," the CON review process itself would not change if either version of Option 4 were adopted. The consortium suggests that Option 4 be amended to avoid expanding the current use of the CON exemption process. Staff concurs that achieving Option 4's primary objective through modifications to the current SHP, rather than through any change to or expansion of the procedural advantages of CON exemption has several advantages.

Working within the current statutory framework of CON exemption for reallocation of existing bed capacity among merged asset system hospitals *through a review and a finding by the Commission* is consistent with procedural incentives given to merged asset hospital systems since 1985. For hospitals not in merged asset system, Option 4 retains the CON requirement for a new obstetrics service but removes the threshold need requirement.

Existing CON standards require an applicant to "provide information and analysis with respect to the impact of the proposed project on existing health care providers [of the same service] in the service area, including the impact on geographic and financial access to services, on occupancy when there is a risk that this will increase costs to the health care delivery system, and on costs and charges of other providers." Due process provisions in existing rules for CON review permit affected facilities to participate in the review as interested parties, who can take judicial appeal if aggrieved by the Commission's decision. Changes to the State Health Plan, needed to guide the review of a proposal on either the exemption or the full CON level, will be developed with public participation, and will factor in all of the challenges and considerations facing hospitals, and the hospital system, in Maryland.

Current statute permits merged hospital systems to move beds across county lines to create a new obstetric (or any non-specialized acute care service) -- *if* the action is "not inconsistent with the State Health Plan," and meets the other statutory tests for CON exemption to permit a "change in type or scope of services" between two members of a merged asset hospital system. Changing the State Health Plan to remove the threshold need requirement will make it possible for the Commission to make such a finding. Staff believes that this action is consistent with the procedural advantages accorded to merged asset systems.

IV. Comparison of Alternative Approaches to Implement Option 4: “Modified CON Oversight of Obstetric Services”

In summary, Option 4 represents a model for modified oversight of proposals for new hospital obstetric services that is responsive to the changing health care environment. Option 4 offers several advantages over both complete deregulation from CON and over keeping the current system with no changes, and will allow for fundamental changes in the review process, while still retaining some authority and policy role in issues of access, quality and cost effectiveness. There are two approaches that could be used to implement Option 4. Original Option 4 would have used an implementation strategy requiring statutory change to create a new use for the exemption process. Amended Option 4 uses an implementation strategy requiring no statutory change but necessitating revisions to the State Health Plan. Table 1 compares the key features of the original and amended implementation strategies for Option 4.

V. Staff Recommended Action

Staff recommends that the Commission adopt Option 4, “Modified CON Oversight of Obstetric Services”, with the amended implementation strategy, as the Commission’s recommendation to the General Assembly regarding the Certificate of Need requirement for new obstetric services. If approved, Commission staff will begin developing the revisions to the State Health Plan necessary to implement Option 4, for the development of new obstetric services. In this way the Commission can respond to the changing health care environment and still retain the public policy benefits of oversight of the health care system.

Table 1. Comparison of Option 4 Implementation Strategies

	Original Implementation Strategy	Amended Implementation Strategy
Statute	<ul style="list-style-type: none"> Remove obstetrics from list of services requiring CON approval Add provisions permitting an exemption finding for approval of a new obstetric service 	<ul style="list-style-type: none"> No change in statute required
Threshold for Review	<ul style="list-style-type: none"> Remove jurisdictional need projection as threshold for review of new obstetric programs through SHP revisions 	<ul style="list-style-type: none"> Remove jurisdictional need projection as threshold for review of new obstetric programs through SHP revisions
Regulations	<ul style="list-style-type: none"> Revise State Health Plan chapter's criteria, policies, and standards regarding access, quality, and cost effectiveness Remove threshold need requirement Revise procedural regulations 	<ul style="list-style-type: none"> Revise State Health Plan chapter's criteria, policies, and standards regarding access, quality, and cost effectiveness Remove threshold need requirement
Process	<ul style="list-style-type: none"> Commission review of CON exemption request for proposed new obstetric service 	<ul style="list-style-type: none"> For merged systems, Commission review of CON exemption request for reallocation of beds For non-system hospitals, Commission review of CON application
Rights of Other Providers	<ul style="list-style-type: none"> Publication of notice Receive comments 	<ul style="list-style-type: none"> Publication of notice In exemption reviews, anyone may submit comments In CON reviews, affected hospitals may participate fully as interested party
Findings	<ul style="list-style-type: none"> Three statutory tests: (1) in the public interest; (2) not inconsistent with SHP; (3) more efficient service delivery 	<ul style="list-style-type: none"> For exemption reviews, the three statutory tests For CON reviews: (a) consistent with SHP; (b) address unmet needs; (c) availability of more cost effective alternatives; (d) viability of proposal, financial and non-financial; (e) compliance with conditions on previous CONs; and (f) impact on existing providers.